

Paul E. Harris and Charles Hesdorffer
Serial No.: 09/726,883
Filed: November 30, 2000
Page 6

REMARKS

Claims 1-5, 8-11 and 13 are pending, with claims 1, 2 and 13 being in independent form. Claims 6, 7 and 12 were previously canceled, without prejudice or disclaimer. By this Amendment, claims 1, 2, 5, 8 and 13 have been amended to place the claims in better form for examination.

Rejection under 35 U.S.C. §112, second paragraph

On page 2 of the August 5, 2004 Office Action, claims 1-5, 8-11 and 13 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner stated that in claims 1, 2 and 13, the recitation of "obtaining blood mononuclear cells through collection of monocytes and monocyte precursors" is nonsensical. The Examiner further stated that monocytes and monocyte precursors might be obtained from blood mononuclear cells but not vice versa as claimed.

The Examiner stated that in claim 5, the cells of step (b) might be washed, but not the "tissue culture" as is recited in the claim.

The Examiner stated that in claim 8, step (d) might be followed by step (e) or the claim might recite "the method of claim 1 further comprising (e) ... (f) ... (g) ...", but it is unclear how step (d) is to include steps (e-g) as recited.

The Examiner stated that in claims 1 and 2, "further processing the dendritic cell culture medium which remain in the container

Paul E. Harris and Charles Hesdorffer
Serial No.: 09/726,883
Filed: November 30, 2000
Page 7

after step (c) and harvesting the processed dendritic cells" is both ungrammatical and nonsensical.

The Examiner stated that in claim 13, it is unclear how "incubating said contents, allowing beads with adherent cells attached thereto after incubation to settle, and then expressing off supernatant including nonadherent cells" comprises a method of "preparing the contents of the cell culture container ... for culturing" as is recited in the claim.

The Examiner further stated that in claim 13, step (d), "incubating the contents of the cell culture container after the additional media are introduced into the cell culture container in step (c), in order to grow dendritic cell culture", is ungrammatical.

By this Amendment, claims 1, 2, 5, 8 and 13 have been amended to place the claims in better form for examination, with particular attention to the points raised by the Examiner. Applicants respectfully submit that the amended claims clearly and distinctly recite the claimed invention.

Accordingly, Applicants respectfully requests that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. §112, second paragraph.

Enablement Rejection

On page 3 of the August 5, 2004 Office Action, claims 1-5, 8-11 and 13 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention.

The Examiner stated that the specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. The Examiner further stated that undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention.

The Examiner stated that the instant invention is drawn to a method of "reproducibly generating dendritic cells (DCs)" comprising a method of cell culture. The Examiner also stated that in vitro generation of dendritic cells was well known in the art at the time of the invention of the instant claims, however, performing the steps of the instant claims would not necessarily result in a product consisting of said cells given the breadth of the claims, i.e., the lack of specific limitations. The Examiner further stated that the method of the instant claims must be considered highly unpredictable and requiring of undue experimentation.

The Examiner stated that step (d) comprises the actual culturing of adherent monocytes to produce DCs. The Examiner further stated that it is clear that the method comprises a method of culturing human DC, the incubation of the adherent monocytes would require the inclusion of specific reagents in the incubation, at minimum GM-CSF and IL-4 or IL-7.

By this Amendment, claims 1, 2, 5, 8 and 13 have been amended to place the claims in better form for examination, with particular attention to the points raised by the Examiner. Applicants respectfully submit that the claimed invention described in the amended claims is fully enabled by the specification.

Accordingly, Applicants respectfully requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §112, first paragraph.

Written Description Rejection

On page 4 of the August 5, 2004 Office Action, claims 1-5, 8-11 and 13 was rejected under 35 U.S.C. §112, first paragraph, as the specification allegedly does not contain a written description of the claimed invention, in that the disclosure purportedly does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The Examiner stated that the specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

- (A) "obtaining blood mononuclear cells through collection of monocytes and monocyte precursors separated substantially from lymphocytes ... [and culturing in media] ... said media including at least rh-GM-CSF", (step a),
- (B) "further processing the dendritic cell culture medium whi8ch remain in the container after step (c) and harvesting the processed dendritic cells", (step d),
- (C) "harvesting the dendritic cell culture from the incubated contents of the cell culture container, including agitating said incubated contents, allowing the beads in

the cell culture container to settle after said agitating, and expressing off cell culture suspension into another container", (step e), and

- (D) in claim 13, step (b), "preparing the contents of the cell culture container, including the medium and the blood mononuclear cells loaded into the cell culture container in step (a), for culturing, by incubating said contents, allowing beads with adherent cells attached thereto after incubation to settle, and then expressing off supernatant including nonadherent cells".

By this Amendment, claims 1, 2, 5, 8 and 13 have been amended to place it in better form for examination. Applicants respectfully submit that the specification reasonably conveys to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §112, first paragraph.

In view of the amendments to the claims and remarks hereinabove, Applicants maintain that claims 1-5, 8-11 and 13 are now in condition for allowance. Accordingly, Applicants earnestly solicit the allowance of the application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorneys invite the Examiner to telephone them at the telephone number provided below.

If a petition for an extension of time is required to make this

Paul E. Harris and Charles Hesdorffer
Serial No.: 09/726,883
Filed: November 30, 2000
Page 11

response timely, this paper should be considered to be such a petition.

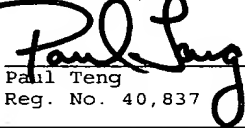
No fee is deemed necessary in connection with the filing of this Amendment. However, if any fees are required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Paul Teng
Reg. No. 40,837

November 5, 2001
Date